

The effectiveness of the Wim Hof Method on the physical and mental health of people with a spinal cord injury

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Spinal cord and nerve root disorders
Study type	Interventional

Summary

ID

NL-OMON51828

Source

ToetsingOnline

Brief title

Wim Hof Method in people with SCI

Condition

- Spinal cord and nerve root disorders

Synonym

spinal cord injury, spinal nerve damage

Research involving

Human

Sponsors and support

Primary sponsor: Revalidatiecentrum Reade

Source(s) of monetary or material Support: Dr. C.J. Vaillant Fonds;W.M. de Hoop Stichting;Ars Donandi/Yske Walther fonds;Reade foundation

Intervention

Keyword: Breathing exercise, Cold exposure, Mindset, Spinal Cord Injuries

Outcome measures

Primary outcome

The primary objective of this RCT is to assess the effects of the WHM, involving breathing exercises, mindset (and cold exposure), on health-related quality of life.

Secondary outcome

The secondary objectives are to assess the effects of the WHM, involving breathing exercises, mindset (and cold exposure) in people with SCI, on:

- markers of metabolic health;
- inflammation markers;
- pulmonary function;
- body composition;
- sleep quality;
- spasticity;
- chronic pain;
- stress.

Study description

Background summary

A spinal cord injury (SCI) is a serious medical condition that causes functional, psychological and socioeconomic disorder. Long-term, secondary medical complications are common and play an important role in the continuum of care for people with SCI. Complications are a frequent cause of morbidity and

mortality and lead to increased rates of rehospitalisation, loss of employability and decreased quality of life. During multidisciplinary SCI rehabilitation, the treatment is focussed on working with the patient physically and psychologically to maximize their neurological recovery and general health but also to prevent or deal with the secondary complications. One of the methods that may help to prevent or deal with secondary complications in people with SCI is the Wim Hof Method (WHM). The WHM is based on three elements: 1) breathing exercises, 2) gradual cold exposure (cold showers, or cold water immersion), and 3) mindset. Previous studies showed a positive effect of the WHM on health-related quality of life and the inflammatory profile of healthy individuals as well as patients with active axial spondyloarthritis. Furthermore, a pilot study in people with SCI showed that the WHM (only breathing exercises and mindset) led to positive changes in respiratory function, mental health index, hyperventilation and a trend was visible regarding the hindrance due to spasticity. Some of the participants mentioned that they experienced positive effects on coughing, energy level, mood or used less spasticity medication after the WHM intervention. These positive findings in the pilot study warrant a full-scale randomised-controlled trial (RCT) of this novel therapeutic approach in people with SCI.

Study objective

The primary objective of this trial is to assess the effects of WHM, involving breathing exercises, mindset (and cold exposure), on health-related quality of life in people with SCI. The secondary objectives are to assess the effects of WHM, involving breathing exercises, mindset (and cold exposure) in people with SCI on: inflammation markers, metabolic health, pulmonary function, body composition, sleep quality, spasticity, stress, and on chronic pain.

Study design

Randomized controlled trial.

Intervention

An RCT design will be used with two intervention groups and one control group. The intervention groups will follow a 7-weeks intervention, with one practice session per week at the rehabilitation center led by Wim Hof or one of his instructors. Besides these joint weekly sessions, the intervention groups have to practice daily at home with the WHM app. The first intervention group will practice the breathing and mindset exercise while the second intervention group will also practice the cold exposure (i.e, breathing, mindset and cold exposure). The control group will not receive any intervention, they will receive usual care and only participate in the pre and post tests.

Study burden and risks

Possible benefits of participating are lower levels of the inflammation markers, improved respiratory function, less hindrance of spasticity, less pain and stress and a better mood. Minor risks of the breathing exercises might be fainting or becoming emotional. Participants will always perform the breathing exercises in a supine position, therefore, there is no risk of falling when fainting. During the pilot study, none of the participants has fainted. Participants will slowly increase the amount of cold exposure. Supervision, by a partner or caretaker, will be present the first time the cold washing cloths or cold shower will be used

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Having a complete or incomplete chronic spinal cord injury

- Age between 18 and 75 years

Exclusion criteria

- Cardiac arrhythmias or cardiac disease;
- A history of severe autonomic dysreflexia assessed with the 'Autonomic standards assessment';
- Severe pulmonary disease (such as COPD) based on a pulmonary history;
- Insufficient mastery of the Dutch language (speaking and reading);
- Severe cognitive or communicative disorders;
- Progressive disease;
- Being or becoming pregnant during the study period;
- Severe psychiatric illness or disorders (at the discretion of the treating rehabilitation physician);
- Involved in another intervention study which may have an effect on the outcome measures of the present study;
- Experience with (parts of) the Wim Hof Method;
- Negative advice from physician to participate in the WHM intervention based on the medical screening.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	28-03-2023
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date: 20-12-2022

Application type: First submission

Review commission: METC Maxima Medisch Centrum (Veldhoven)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL81525.015.22